



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,466	04/26/2001	Hiroyasu Kokubo	35576/233803	8005

826 7590 02/03/2003

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 02/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/842,466

Applicant(s)

KOKUBO ET AL.

Examiner

Humera N Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002 (paper no.8).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION
Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 11/25/02.

Claims 1 and 6-20 are pending. Claim 1 has been amended. Claims 1 and 6-20 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the applicant is intending to convey with the phrase "continuous coating." While one can understand a "single coating", it is unclear as to how a medicament comprising two colors can be continuous. Clarification is requested.

The term "*single*" as amended by the applicant (11/25/02), is not supported by the instant specification. The instant specification simply contains the phrase "film coating"; however, the term "single" is not contained anywhere in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-8 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Berta (US Pat. No. 4,820,524).

Berta discloses a solid, multi-colored medicament preparation having a gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 39-42).

The medicament may be in the form of a caplet and contains a layer of gelatin as a single coating on the caplet core.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1615

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berta (US Pat. No. 4,820,524).

As discussed above, Berta teaches a solid, multi-colored medicament preparation having a gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 39-42).

Berta also teaches a method for coating the solid cores, such as caplets, to produce simulated, capsule-like medicaments. Berta teaches that one objective of the invention is to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colors. Another objective is to provide a heavy layer of gelatin as a *single* coating to cover imperfections inherent on the caplet core (col. 4, lines 12-56). Suitable coatings to be used are gelatinous materials, such as methyl cellulose, calcium alginate and gelatin. Additional ingredients include plasticizers, preservatives, coloring agents and opacifying agents (col. 8, lines 20-47).

Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce *opaque* or *transparent* colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. Colored medicaments are necessary to give a specialty product a distinctive appearance. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin (col. 9, lines 1-7).

Berta teaches that the solid, multi-colored medicament preparation additionally comprises various coating patterns (see Figs. 8a-d and col. 5, lines 28-29). Berta does not explicitly teach a logo, letters or a bar code on the medicament. However, the inclusion of logos, bar codes or letters, as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practiced in the pharmaceutical art.

Berta teaches a solid preparation comprising a gelatinous coating that provides two or more colors wherein the medicament is smooth, shiny, multi-colored and has various coating patterns. These medicaments are pleasing to the eye, are easier to swallow than prior medicaments and offer a distinctive appearance, as similarly desired by the applicant.

C rrespondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

HNS
January 30, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER-1600